

CLAIMS

1. A quality control method for a spectrophotometer, comprising the steps of:
 - 5 determining with the spectrophotometer an absorption spectrum $A_m(\lambda)$ of a fluid quality control sample containing a dye selected from such dyes which provide the quality control sample with an absorption spectrum with a significant absorbance peak showing a steep flank, and
 - 10 determining a wavelength shift $\Delta\lambda$ between the absorption spectrum $A_m(\lambda)$ of the actually measured quality control sample and a reference absorption spectrum $A_0(\lambda)$ of a reference quality control sample containing the dye stored in a memory of the spectrophotometer.
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- 20 2. A method according to claim 1, wherein the wavelength shift $\Delta\lambda$ is determined from $A_m(\lambda)$ and a predetermined mathematical parameter stored in the memory of the spectrophotometer.
- 25 3. A method according to claim 2, wherein the mathematical parameter is a coefficient vector $C_{\Delta\lambda}(\lambda)$ and wherein the wavelength shift $\Delta\lambda$ is determined from $C_{\Delta\lambda}(\lambda) \cdot A_m(\lambda)$.
- 30 4. A method according to claim 3, wherein the vector $C_{\Delta\lambda}(\lambda)$ fulfills the equation

$$\Delta\lambda = C_{\Delta\lambda}(\lambda) \cdot A_m(\lambda)$$

5. A method according to claim 4, wherein $C_{\alpha}(\lambda)$ has been determined from a Taylor series of the reference absorption spectrum $A_0(\lambda)$.

5 6. A method according to claim 5, wherein $C_{\alpha}(\lambda)$ has been determined from a combination of the reference absorption spectrum $A_0(\lambda)$ and a first derivative $A_0'(\lambda)$ of said reference absorption spectrum.

10 7. A method according to any of the preceding ~~claims~~ ^{claims} 1-6, wherein the wavelength shift $\Delta\lambda$ is determined after normalisation of the determined spectrum $A_m(\lambda)$ with an estimate of the concentration of the dye.

15 8. A method according to any of the preceding ~~claims~~ ^{claims} 1-7, wherein the quality control sample has an assigned wavelength shift $\Delta\lambda_{qc}$, which method further comprises the step of comparing $\Delta\lambda$ with $\Delta\lambda_{qc}$.

20 9. A method according to any of the preceding ~~claims~~ ^{claims} 1-8, wherein the quality control sample has a known dye concentration c_{qc} and the dye comprises a first and a second component, the method further comprising the steps of

25 calculating parameters s_1 and s_2 from

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$$s_1 = C_1(\lambda) \bullet A_m(\lambda)$$

$$s_2 = C_2(\lambda) \bullet A_m(\lambda)$$

35 in which $C_1(\lambda)$ and $C_2(\lambda)$ are predetermined vectors previously stored in the memory of the spectrophotometer, and

calculating an estimated concentration c_{est} of the dye from

5 $c_{est} = a s_1 + b s_2$

in which a and b are predetermined constants previously stored in the memory of the spectrophotometer.

10 10. A method according to claim 9, further comprising the step of comparing c_{est} with c_{qc} .

15 11. A method according to ~~claims 9-10~~, further comprising the step of calculating a variable $Q_{est} = s_2/s_1$.

20 12. A method according to ~~any of claims 9-11~~, wherein the quality control sample has an assigned value of $Q_{qc} = s_2/s_1$, which method further comprises the step of comparing Q_{est} with Q_{qc} .

25 13. A method according to ~~any of the preceding claims~~ ¹¹⁻¹², wherein the spectrophotometer is an oximeter.

30 14. A method according to claim 13, wherein spectra are measured in the wavelength range from 400 to 800 nm.

15. A method according to ~~claims 13 or 14~~, further comprising the step of determining estimated errors in blood parameter values reported by the oximeter caused by the wavelength shift $\Delta\lambda$, option-

ally corrected by the assigned wavelength shift $\Delta\lambda_{qc}$.

16. A method according to ~~any of the preceding claims 13-15~~, further comprising the step of determining estimated errors in blood parameter values reported by the oximeter caused by a difference between c_{est} and c_{qc} .

10 17. A method according to ~~any of the preceding claims 13-16~~, further comprising the step of determining estimated errors in blood parameter values reported by the oximeter caused by a difference between Q_{est} and Q_{qc} .

15 18. A method according to ~~any of the preceding claims 1-17~~ further comprising the steps of:

20 determining a first reference absorption spectrum $A_{01}(\lambda)$ of a reference sample containing a dye in a first concentration with a reference spectrophotometer,

25 determining a first derivative $A_{01}'(\lambda)$ of the first reference spectrum, and

30 determining from at least the first reference spectrum $A_{01}(\lambda)$ and the first derivative $A_{01}'(\lambda)$ a mathematical parameter from which a wavelength shift $\Delta\lambda$ of the spectrophotometer can be determined, and

storing the mathematical parameter in a memory of the spectrophotometer.

19. A method according to claim 18, wherein the step of determining the mathematical parameter comprises the steps of

5 calculating a set of calibration vectors $B_i(\lambda)$ according to

$$B_i(\lambda) = s_i A_{01}(\lambda) + s_{i3} A_{01}'(\lambda)$$

10 in which $i = 1, 2, \dots, N$ ($N > 1$) and s_i and s_{i3} are constants of selected values,

15 determining a coefficient vector $C_{\Delta}(\lambda)$ constituting the mathematical parameter so that each set of corresponding values s_{i3} , B_i satisfies:

$$s_{i3} = C_{\Delta}(\lambda) \cdot B_i(\lambda), \quad i = 1, 2, \dots, N$$

20. 20. A method according to claim 18, wherein the dye comprises a first component and a second component, and further comprising the step of determining a second reference spectrum $A_{02}(\lambda)$ of a second reference sample containing the dye in a second concentration with the reference spectrophotometer, and wherein the step of determining a mathematical parameter comprises the steps of

25 calculating a set of vectors $B_i(\lambda)$ from

$$B_i(\lambda) = s_{i1} A_1(\lambda) + s_{i2} A_2(\lambda) + s_{i3} A_0'(\lambda)$$

30 in which $A_1(\lambda)$ and $A_2(\lambda)$ are derived from the first and second reference spectra $A_{01}(\lambda)$, $A_{02}(\lambda)$ and represent spectral information about the first and second components, respectively, and

i=1,2,...,N, and s_{i1} , s_{i2} and s_{i3} are constants of selected values,

5 determining a vector $C_{\Delta\lambda}(\lambda)$ constituting the mathematical parameter so that

$$s_{i3} = C_{\Delta\lambda}(\lambda) \cdot B_i(\lambda)$$

10 21. A spectrophotometer comprising a processor that is adapted to determine the wavelength shift $\Delta\lambda$ between an absorption spectrum $A_m(\lambda)$ determined with the spectrophotometer on a fluid quality control sample containing a dye selected from such dyes which provide the quality control sample with an absorption spectrum with a significant absorbance peak showing a steep flank and a reference absorption spectrum $A_0(\lambda)$ of a reference quality control sample containing the dye, stored in the memory of the spectrophotometer.

15 22. A spectrophotometer according to claim 21, wherein the wavelength shift $\Delta\lambda$ is determined from $A_m(\lambda)$ and a predetermined mathematical parameter stored in the memory of the spectrophotometer.

20 23. A spectrophotometer according to claim 22, wherein the mathematical parameter is a coefficient vector $C_{\Delta\lambda}(\lambda)$ and wherein the wavelength shift $\Delta\lambda$ is determined from $C_{\Delta\lambda}(\lambda) \cdot A_m(\lambda)$.

25 24. A spectrophotometer according to claim 23, wherein the vector $C_{\Delta\lambda}(\lambda)$ fulfills the equation

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$$\Delta\lambda = C_{\Delta\lambda}(\lambda) \cdot A_m(\lambda)$$

25. A spectrophotometer according to claim 24, wherein $C_{\Delta\lambda}(\lambda)$ has been determined from a Taylor series of the reference absorption spectrum $A_0(\lambda)$.

5 26. A spectrophotometer according to claim 25, wherein $C_{\Delta\lambda}(\lambda)$ has been determined from a combination of the reference absorption spectrum $A_0(\lambda)$ and a first derivative $A_0'(\lambda)$ of said reference absorption spectrum.

10 27. A spectrophotometer according to ~~any of the preceding claims 21-26~~, wherein the wavelength shift $\Delta\lambda$ is determined after normalisation of the determined spectrum $A_m(\lambda)$ with an estimate of the concentration of the dye.

15 28. A spectrophotometer according to ~~any of the preceding claims 21-27~~, wherein the quality control sample has an assigned wavelength shift $\Delta\lambda_{qc}$, and wherein the processor is adapted to compare $\Delta\lambda$ with $\Delta\lambda_{qc}$.

20 29. A spectrophotometer according to ~~any of the preceding claims 21-28~~, wherein the quality control sample has a known dye concentration c_{qc} and the dye comprises a first and a second component, and wherein the processor is adapted to

25 calculate parameters s_1 and s_2 from

30 $s_1 = C_1(\lambda) \cdot A_m(\lambda)$

$s_2 = C_2(\lambda) \cdot A_m(\lambda)$

in which $c_1(\lambda)$ and $c_2(\lambda)$ are predetermined vectors previously stored in the memory of the spectrophotometer, and

5 calculate an estimated concentration c_{est} of the dye from

$$c_{est} = a s_1 + b s_2$$

10 in which a and b are predetermined constants previously stored in the memory of the spectrophotometer.

15 30. A spectrophotometer according to claim 29, wherein the processor is further adapted to compare c_{est} with c_{qc} .

20 31. A spectrophotometer according to ~~claims 29 or 30~~, wherein the processor is further adapted to calculate a variable $Q_{est} = s_2/s_1$.

25 32. A spectrophotometer according to ~~any of claims 29 or 30~~, wherein the quality control sample has an assigned value of $Q_{qc} = s_2/s_1$ and wherein the processor is further adapted to compare Q_{est} with Q_{qc} .

30 33. A spectrophotometer according to ~~any of the preceding claims 21-32~~ which is an oximeter.

34. A spectrophotometer according to claim 33, wherein spectra are measured in the wavelength range from 400 to 600 nm.

35 35. A spectrophotometer according to ~~claims 33 or 34~~, wherein the processor is adapted to determine es-

timated errors in blood parameter values reported by the spectrophotometer caused by the wavelength shift $\Delta\lambda$, optionally corrected by the assigned wavelength shift $\Delta\lambda_{qc}$.

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36. A spectrophotometer according to ~~any of the preceding claims 33-35~~, wherein the processor is further adapted to determine estimated errors in blood parameter values reported by the spectrophotometer caused by a difference between c_{est} and c_{qc} .

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37. A spectrophotometer according to ~~any of the preceding claims 33-36~~, wherein the processor is further adapted to determine estimated errors in blood parameter values reported by the spectrophotometer caused by a difference between Q_{est} and Q_{qc} .

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38. A spectrophotometer according to ~~any of the preceding claims 21-37~~ for the determination of a concentration c_y of a component y of a sample and wherein the memory further comprises

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at least one vector $A_{int}(\lambda)$ representing spectral information of an interfering component in the sample at a concentration c_{ref} , and

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at least one predetermined vector $K_{int}(\lambda)$, and

the processor is further adapted to

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calculate the concentration c_{int} of the interfering component according to

$$c_{int} = K_{int}(\lambda) \cdot A_{int}(\lambda), \text{ and}$$

5 if c_{int} is greater than a predetermined threshold value, c_{ref} , calculate a modified absorbance spectrum $A_{mod}(\lambda)$ according to

$$A_{mod}(\lambda) = A_{int}(\lambda) - \frac{c_{int}}{c_{ref}} A_{int}(\lambda), \text{ and}$$

10 determine c_y from the modified spectrum $A_{mod}(\lambda)$ according to

$$c_y = K_y(\lambda) \cdot A_{mod}(\lambda),$$

15 where $K_y(\lambda)$ is a predetermined vector and whereby the effect of interfering components on determined concentrations c_y is minimised.

39. A spectrophotometer according to claim 38, wherein
20 the interfering component is fetal hemoglobin.

40. A spectrophotometer according to ~~any of the preceding claims 21-39~~ further comprising a spectral lamp for emission of light with at least one spectral line, and a processor, including a memory, that is adapted to determine the wavelength of the at least one spectral line and to compare the determined wavelength of said at least one spectral line with the assigned wavelength from an initial calibration procedure of said spectral line stored in the memory of the spectrophotometer, calculate a wavelength shift, and compensate the determined absorption spectrum of said sample for said wavelength shift.

41. A spectrophotometer according to claim 40, which is an oximeter, and wherein the spectral lamp emits light with at least one spectral line in the wavelength range 460-670 nm, and said oximeter is further provided with at least two photodiodes each of which converts the emitted light from the spectral lamp into a current substantially proportional to the light intensity which strikes the photodiode, and wherein the processor of said oximeter calculates the ratio F_{neon} between the two photodiode currents.

42. A spectrophotometer according to claim 41, wherein said spectral lamp is a neon lamp which is activated when the temperature of the spectrometer deviates more than a critical temperature difference, such as more than about 0.2-0.5°C from the previous F_{neon} measurement.